agents being investigated by DA for biological defense purposes.

(b) Specific biological safety requirements and guidance are contained in DA Pam 385–69.

§ 626.6 Mishap reporting and investigation.

Biological defense RDTE related mishaps will be reported and investigated per AR 385–40 and AR 40–400. Med 16 Report will be used to report only personnel exposure or illness related to the BDP.

§ 626.7 Administrative and work practice controls.

(a) The cardinal principle for safety in BDP operations is to minimize the potential exposure of personnel to etiologic agents. In practice, this means conducting RDTE activities using the appropriate facilities, equipment, and procedures for the biosafety level (BL), and requiring only the minimum number of appropriately trained personnel, the minimum period of time, and minimum amount of the material, consistent with program objectives and safe operations.

(b) Open air testing under the BDP is restricted to use of simulants only, unless the Secretary of Defense determines that testing is necessary for national security in accordance with section 409, Public Law 91–121, 83 Stat. 204, signed November 18, 1967. Also, for RDTE involving protective equipment or detection devices, the least hazardous etiologic agent consistent with mission objectives will be employed. All testing of such equipment employing etiologic agents will be in appropriate biosafety level containment laboratories.

(c) A hazard analysis, to determine safety precautions, necessary personnel protection and engineering features, and procedures to prevent exposure, will be completed for—

(1) All BDP operations involving etiologic agents.

(2) A change in process or control measures that may increase potential contact or concentrations of biological material.

(d) An SOP is required for all biological defense RDTE operations. The SOP will—

(1) Describe in detail all necessary operational and safety requirements.

(2) Describe in detail actions to take in the event of mishap.

(3) Describe in detail the location of required emergency response equipment.

(4) Be available at the work site.

(5) Forbid concurrent unrelated work during biological defense RDTE operations within a laboratory area or suite.

(6) Be approved by the commander or the safety officer and signed by workers involved in the operation.

(7) Provide names and telephone numbers of responsible personnel.

(e) Training and information. All personnel who work directly with etiologic agents in the BDP, or who otherwise have a potential for exposure, will receive appropriate training to enable them to work safely and to understand the relative significance of agent exposures.

(1) This training will include signs and symptoms of etiologic agent exposure, information on sources of exposure, possible adverse health affects, and practices and controls used to limit exposures. The environmental and medical monitoring procedures in use, their purposes, worker responsibilities in health protection programs, and handling of laboratory mishaps will also be presented.

(2) Workers will be required to demonstrate proficiency before performing potentially hazardous operations. Refresher training will be repeated at least annually.

(3) Initial and refresher training will be documented and kept on file as a permanent record.

(f) Medical surveillance. A medical surveillance program (see AR 40–5) will be established for all personnel (military and civilian) who may be potentially exposed to etiologic agents.

(1) Placement, periodic medical surveillance examinations, and termination examinations shall be conducted for each worker, to establish a baseline health record and to provide periodic job-related assessments of the worker's health status. Preassignment, periodic, and termination health assessments will include a work history,

a medical history, physical examinations, indicated clinical laboratory sutdies and, when available, examinations or tests specific to the etiologic agent in question.

(2) Medical officers responsible for treating BDP etiologic agent exposures and conducting medical surveillance for BDP workers shall receive specialized training on the unique hazards of etiologic agents and recommended medical therapies.

(3) Special immunizations will be given to personnel handling specific etiologic agents as required.

(4) Records documenting the above will be maintained permanently.

(g) Emergency preparedness: (1) SOPs will address emergency procedures related to any mishap involving BDP etiologic agents. Notification and evacuation procedures will be covered in detail, as well as measures to contain the contamination.

(2) Local, regional, State, or Federal emergency support and coordinating agencies, such as law enforcement, fire departments, health departments, and governments will be informed of BDP activities and the appropriate support necessary, to include any equipment and training necessary, to provide effective emergency response and ensure compliance with community ''right-to-know'' statutes and regulations. Agreements with external agencies must be formalized.

(3) If a mishap with a BDP etiologic agent results in personnel exposure, approved emergency procedures will be immediately initiated to protect personnel and the environment and to constrain the spread of contamination. All personnel except those responsible for emergency operations will evacuate the immediate area.

(4) Special medical surveillance will be started as soon as possible for all workers present in the potentially affected area at the time of the mishap.

(h) Labeling and posting of hazards:

(1) Hazard warning signs which incorporate the universal biohazard symbol will be posted on the access door to the work area. (See DA PAM 385–69, para 3–5a(1).) The sign will be covered or removed if the organizational safety officer certifies that the area has been decontaminated.

(2) For areas irradiated with ultraviolet light, a caution sign reading ''Ultraviolet Light, Wear Eye Protection'' will be posted.

(i) Disposal controls. Etiologic agents used in the BDP must be decontaminated before disposal of infectious or hazardous wastes and must not violate any Army, Federal, State, local, or host nation environmental standards. Procedures for decontamination are described in DA Pam 385–69.

(1) The preferred methods of decontamination of etiologic agents are autoclaving or chemical inactivation with appropriate biocidal solutions. (See chap 5, DA Pam 385–69.)

(2) Etiologic agents awaiting decontamination will be contained at the appropriate biosafety level.

(j) Maintenance controls. A continuing program for equipment and facility maintenance will be implemented for each BDP operation.

(k) Protective equipment. Guidance concerning protective equipment is contained in DA Pam 385–69.

§ 626.8 Etiologic agent containment.

(a) Facility engineering controls and appropriate biocontainment equipment will be used, in conjunction with special practices and procedures, to minimize potential exposure of personnel and the environment to etiologic agents used in BDP operations. Engineering and equipment controls will be implemented to the maximum extent feasible and verified as effective. Protective clothing will not be used in lieu of engineering controls. Engineering controls will be the prime means of biocontainment. Personal protective equipment such as respirators are to be used only after feasible engineering controls have been shown unable to control the environment fully.

(b) Before beginning any etiologic agent operation, a determination will be made that the hazards associated with the operation are under positive control as defined in the applicable SOP and that the operation complies with the criteria of this regulation and DA Pam 385–69.

§ 626.9 Inspections.

(a) Biosafety laboratories require periodic (at least quarterly for BL–1